UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF PENNSYLVANIA

ANTHONY GEORGE, individually and on behalf of all others similarly situated, Plaintiff, v. KONINKLIJKE PHILIPS N.V., PHILIPS NORTH AMERICA LLC, and PHILIPS RS NORTH AMERICA LLC, Defendants.	Civil Action No. 2:21-cv-1359 **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT

Plaintiff Anthony George, individually and on behalf of all others similarly situated, through undersigned counsel, alleges as follows.

I. NATURE OF THE ACTION

1. Defendants Koninklijke Philips N.V., Philips North America LLC, and Philips RS North America LLC (collectively, "Philips") manufacture and sell a variety of products that are intended to help people breathe. These include Continuous Positive Airway Pressure ("CPAP") and Bilevel Positive Airway Pressure ("BiPAP") machines, which are commonly used to treat sleep apnea, and ventilators, which treat respiratory failure. In general, all of these devices blow air into patients' airways. CPAP and BiPAP machines are intended for daily use while sleeping, and ventilators are used continuously while needed. Without these devices, patients may experience severe symptoms including heart attack, stroke, and death by asphyxiation.

2. On June 14, 2021, Philips announced a recall of millions of its CPAP/BiPAP machines and ventilators. These products contain polyester-based polyurethane ("PE-PUR") foam for sound abatement. Philips announced that the foam may break down and be inhaled or ingested,

or may emit volatile organic compounds ("VOCs") that may be inhaled, resulting in adverse effects to organs or cancer. Philips stated that the potential risks of exposure due to such chemical emissions include "headache/dizziness, irritation (eyes, nose respiratory tract, skin), hypersensitivity, nausea, vomiting, toxic and carcinogenic effects. Philips' announcement to doctors advised that these hazards could result in "serious injury which can be life-threatening or cause permanent impairment."

3. On July 22, 2021 the U.S. Food and Drug Administration ("FDA") confirmed the severity of the problem, and classified the recall of Philips' breathing devices at issue as a Class I recall, or "the most serious type of recall," meaning use of the devices "may cause serious injuries or death."[1]

4. In truth, Philips knew about these very serious risks long before the recall. Patients who use the affected devices have complained about black particles in their machines for many years. And while Philips notified its shareholders about the defect in late April 2021, it did not recall its machines until June 14, 2021.

5. Philips' recall is a "recall" in name only and Philips has failed its customers in every way since providing its late notice of the problems. For example, Philips has not offered its customers a refund for their purchase of the recalled devices so that they can purchase an alternative breathing machine. Nor has Philips actually replaced or repaired any of the affected devices. Although patients need to use their devices every day, Philips has no concrete timeline for replacing any devices and may not provide replacements or repairs for a year or more.

[1] https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-continuous-and-non-continuous-ventilators-including-cpap-and.

6. In fact, it appears that Philips timed its recall to coincide with its launch of a next generation of the affected products, which Philips claims does not suffer from the same foam issues. Thus, the only safe option that Philips currently offers to its customers—many of whom need a BiPAP/CPAP machine to sleep—is to purchase, at full price, Philips' new, next-generation device, thus profiting Philips further.

7. Because of the increased demand and shortage of microchips, replacement machines are very difficult to find and only available at inflated prices. Many users have thus been forced by Philips into a Hobson's choice—continue using Philips' recalled machines exposing themselves to a risk of serious injury or death, or stop using Philips' recalled machines exposing themselves to a risk of serious injury or death.

8. Plaintiff acquired a device that Philips has now recalled. He would not have obtained the device at the price that he paid, or at all, if he had known that the PE-PUR foam in the device could cause serious injury or death.

9. Plaintiff, on behalf of himself and other similarly situated individuals who also paid for the defective devices, seek to recover damages from Philips based on strict liability, negligence, breach of express warranty, breach of implied warranty, unjust enrichment, and applicable state consumer protection and deceptive trade practices statutes. Plaintiff also seeks medical monitoring damages for users of devices.

10. Plaintiff brings this Class Action Complaint to represent a class of similarly situated persons defined below, who also purchased the defective Recalled Products, and to obtain relief for their injuries.

II. PARTIES

A. PLAINTIFF

10. Plaintiff Anthony George resides in Wilmington, Delaware. In or around April 2019, Plaintiff acquired a recalled Philips BiPAP to treat sleep apnea. Plaintiff George would not have obtained the device if Plaintiff George had known it was defective. Plaintiff purchased a replacement machine from a different manufacturer out-of-pocket and wants a refund, replacement with a non-defective device, costs for ongoing medical monitoring, and all other appropriate damages for all the injuries suffered as a result of the defective device.

B. DEFENDANTS

11. Koninklijke Philips N.V. is a Dutch multinational company headquartered in Amsterdam, Netherlands, and is the parent company of Philips North America LLC and Philips RS North America LLC.

12. Defendant Philips North America LLC is a Delaware company with its principal place of business in Cambridge, Massachusetts.

13. Defendant Philips RS North America LLC (formerly Respironics, Inc.) is a Delaware company headquartered in Pittsburgh, Pennsylvania.

14. Reference to "Philips," "Defendant," or "Defendants" refers to each and every Defendant individually and collectively.

III. JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over this class action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds $5 million, exclusive of interest and costs, and is a class action in which Plaintiff and some members of the Class are citizens of states different than Defendants. *See* 28 U.S.C. § 1332(d)(2)(A).

16. Venue is proper in this District because Philips RS North America LLC is headquartered in this District and because a substantial part of the events or omissions giving rise to the claim occurred in this District.

IV. FACTUAL ALLEGATIONS

A. CPAP MACHINES, BIPAP MACHINES, AND VENTILATORS TREAT SERIOUS CONDITIONS.

17. Sleep apnea is a sleeping disorder in which breathing is disturbed temporarily during sleep. Breathing may stop or become very shallow. These disturbances are called "apneas."

18. According to the Mayo Clinic, the main types of sleep apnea are obstructive sleep apnea, central sleep apnea, and complex sleep apnea syndrome (also known as treatment-emergent central sleep apnea).

19. Obstructive sleep apnea is the most common type. It occurs when the muscles in the back of the throat relax during inhalation, which causes the airway to narrow or close and prevent sufficient air from passing through. This in turn lowers the oxygen level in the blood, which causes the brain to briefly wake the body from sleep to reopen the airway. This reawakening may be so brief that the patient does not remember it, and it may be associated with snorting, choking, or gasping. It can happen anywhere from a few times per hour to once every few minutes, all night, and can prevent the patient from reaching the deep, restful phases of sleep.

20. Central sleep apnea occurs when the brain fails to transmit signals to the breathing muscles. As a result, the body stops breathing temporarily, which can cause waking with shortness of breath or difficulty getting to sleep or staying asleep.

21. Complex sleep apnea syndrome occurs when a patient has both obstructive sleep apnea and central sleep apnea.

22. Sleep apnea is a serious medical condition that can cause daytime fatigue, high blood pressure or heart problems, stroke, type 2 diabetes, metabolic syndrome, complications with medications and surgery, liver problems, snoring or other noises during sleep, and other medical ailments.

23. CPAP therapy is a common treatment for sleep apnea. In CPAP therapy, a machine delivers a flow of air through a mask over the nose or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea.

24. Other therapies to treat sleep apnea include BiPAP and Automatic Positive Airway Pressure (APAP). BiPAP machines use two different pressures, one for inhaling and one for exhaling. APAP machines adjust pressure automatically throughout the night to the patient's pressure needs, for example, in response to changed sleeping positions or different sleep stages. Not every therapy is appropriate for every patient. Many patients respond well to one treatment and not others.

25. Patients usually place the CPAP, BiPAP, or APAP machines on a nearby nightstand or shelf. A hose connects the unit to the mask, which is worn over the nose or mouth during sleep.

26. Patients who use CPAP or BiPAP machines typically must use them every day when they sleep. Symptoms may return quickly if therapy is discontinued.

27. Respiratory failure is a condition in which a patient has difficulty breathing or getting enough oxygen into the blood. Many underlying conditions can cause respiratory failure, including physical trauma, sepsis, pneumonia, COVID-19, and drug overdose. Respiratory failure can be fatal.

28. Mechanical ventilators, usually called "ventilators," are often used to treat respiratory failure. Ventilators push air into and out of the patient's lungs like a bellows, typically through a tube that is connected to the machine on one end and is inserted through the patient's nose or mouth into the trachea on the other end. Patients are usually sedated while on ventilation because it can otherwise cause intense pain.

29. Ventilators can also be used in other circumstances, such as during surgery when general anesthesia may interrupt normal breathing. Ventilators intended for home use also exist.

30. The COVID-19 crisis has led to a significant increase in the demand for ventilators because severe COVID-19 can cause sufficient damage to the lungs that patients have difficulty breathing on their own and thus require a ventilator.

B. PHILIPS SELLS CPAP AND BIPAP MACHINES AND VENTILATORS CONTAINING PE-PUR FOAM.

31. Philips manufactures and sells CPAP machines, BiPAP machines, and ventilators, among other products. According to Philips' 2020 Annual Report,[2] Sleep & Respiratory Care constituted 49% of Philips' total sales in its Connected Care line of business, which in turn accounted for 28% of Philips' overall sales of about €19.535 billion. Philips has sold millions of CPAP and BiPAP machines and ventilators in the United States.

32. Philips' flagship CPAP/BiPAP machine product family is the DreamStation family, including the original DreamStation, launched in October 2015, and the DreamStation Go (a travel version). Philips sells DreamStation products through its subsidiary, Respironics, which Philips acquired in 2008 and is now known as Philips RS North America LLC. The user manual for the

[2]https://www.philips.com/c-dam/corporate/about-philips/investors/shareholder-info/agm-2021/Philips%20Annual%20Report%202020.pdf.

DreamStation products is marked with a copyright notice indicating that Koninklijke Philips, N.V. owns the copyright to the manual.

33. Philips markets the recalled DreamStation products under an approval from the FDA. Philips submitted premarket notification of intent to market medical devices under Section 510(k) of the Federal Food, Drug, and Cosmetic Act. Based on Philips' submission, the FDA "determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA)."

34. Under this regulatory framework, the devices did not have to undergo a detailed review for safety and efficacy.

35. The FDA classifies medical devices as Class I, II, or III, based on the risk to the patient, the intended use, and the indications for use. Class I devices are the lowest risk and Class III devices are the highest risk. The FDA classified the DreamStation products as Class II devices. Other recalled products (listed below) are Class II or Class III devices.

36. Many of Philips' CPAP and BiPAP machines and ventilators contain PE-PUR foam for sound abatement. Polyurethane is an organic polymer in which urethane groups connect the molecular units, and it is usually formed by reacting a diisocyanate or triisocyanate with a polyol. Under certain circumstances, polyurethane may break down into a diisocyanate or triisocyanate as well.

37. The two main types of polyurethane are polyester and polyether. Polyester polyurethane has much better shock absorption and vibration dampening properties and is commonly used for soundproofing or sound dampening.

38. The recalled devices contain polyester polyurethane foam for sound dampening.

39. In the DreamStation, for example, there is a channel that surrounds the central fan in the device. This channel is stuffed with PE-PUR foam to absorb the noise from the device while the patient is sleeping. Air passes through this channel, and thus through the PE-PUR foam, before it enters the fan and is pumped into the patient's airway.

40. Philips advertises itself as a trusted brand and "global leader in the sleep and respiratory markets."[3] Its branding promises consumers that they will "[b]reath easier, sleep more naturally[.]"[4] Philips further assures consumers that its "sleep therapy systems are designed with the needs of care practitioners and patients in mind," and that its "quality systems reflect [Philips'] commitment to providing exceptional therapy," among other things. And it has long advertised its CPAP and BiPAP Machines as "clinically proven" treatment for sleep disorders.[5]

41. Philips boasts that it has the "most prescribed PAP systems by U.S. sleep physicians."[6] The machines routinely cost from seven or eight hundred dollars to thousands of dollars per machine.

C. PHILIPS RECALLED ITS PE-PUR FOAM-CONTAINING MACHINES DUE TO SERIOUS HEALTH HAZARDS THAT THEY CAUSE.

42. On April 13, 2021, Philips announced that it was launching the DreamStation 2, a next-generation machine in its DreamStation product family.

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[3] *See* http://www.respironics.com/us_en.
[4] http://www.respironics.com/product_library.
[5] https://www.usa.philips.com/healthcare/solutions/sleep.
[6] *See* https://www.usa.philips.com/healthcare/solutions/sleep/sleep-therapy (citing 2016 Philips survey).

43. Less than two weeks later, on April 26, 2021, Philips announced that its previous generation products posed serious health risks to users and, in the same release, started trying to convince consumers to purchase its latest generation device:

> Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone,* and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks. Given the estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.

44. On June 14, 2021, Philips issued a further announcement, stating:

> To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone,** and high heat and high humidity environments may also contribute to foam degradation.
>
> Therefore, Philips has decided to voluntarily issue a recall notification* to inform patients and customers of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.

45. Philips stated that "[t]he majority of the affected devices within the advised 5-year service life are in the first-generation DreamStation product family." Philips elaborated:

> Based on the latest analysis of potential health risks and out of an abundance of caution, the recall notification advises patients and customers to take the following actions:
>
> For patients using affected BiLevel PAP and CPAP devices: Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician

to determine if the benefit of continuing therapy with your device outweighs the risks identified in the recall notification.

For patients using affected life-sustaining mechanical ventilator devices: Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks identified in the recall notification.

Possible health risks

The company continues to monitor reports of potential safety issues as required by medical device regulations and laws in the markets in which it operates. To date, there have been no reports of death as a result of these issues. Philips has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects. Philips has received no reports regarding patient impact related to chemical emissions.

46. The recalled products ("Recalled Products") are:

- E30
- DreamStation ASV
- DreamStation ST, AVAPS
- SystemOne ASV4
- C Series ASV, S/T, AVAPs
- OmniLab Advanced Plus
- SystemOne (Q Series)
- DreamStation CPAP, Auto CPAP, BiPAP
- DreamStation Go CPAP, APAP
- Dorma 400, 500 CPAP
- REMStar SE Auto CPAP

- Trilogy 100 and 200
- Garbin Plus, Aeris, LifeVent
- A-Series BiPAP Hybrid A30
- A-Series BiPAP V30 Auto
- A-Series BiPAP A40
- A-Series BiPAP A30

47. The recall notice stated that "Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam."

48. Philips explained: "Based on Philips [*sic*] analysis, the root cause of this issue is related to the sound abatement foam currently used in specific identified products of the Sleep & Respiratory Care portfolio."

49. On the same day, Philips provided additional information in an announcement entitled "Clinical information for physicians," that explained that the foam breakdown "may lead to patient harm and impact clinical care." It adds:

> While there have been limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection that may have been associated with the foam, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.

50. The announcement detailed two types of hazards from the foam in the devices. First, the announcement described dangers due to foam degradation exposure:

> **Potential Hazard:** Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in

> certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.
>
> The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:
>
> - Toluene Diamine
>
> - Toluene Diisocyanate
>
> - Diethylene glycol

51. Millions of patients across the United States used and trusted the Recalled Products on a nightly basis while they slept. Philips has now revealed that the PE-PUR foam in their breathing machines degraded in Defendants' devices and the poisonous particles were aspirated by these patients.

52. The fact that the patients breathed in toxic and poisonous chemicals is not reasonably in dispute. According to the Report on Carcinogens, Fourteenth Edition, by the National Toxicology Program in the United State Department of Health and Human Services, toluene diisocyanates are reasonably anticipated to be human carcinogens based on sufficient evidence of carcinogenicity from studies in experimental animals. Administration of commercial-grade toluene diisocyanate (analyzed as 85% 2,4 isomer and 15% 2,6 isomer) by stomach tube caused liver tumors (hepatocellular adenoma) in female rats and mice, benign tumors of the mammary gland (fibroadenoma) and pancreas (islet-cell adenoma) in female rats, and benign tumors of the pancreas (acinar-cell adenoma) in male rats. It also increased the combined incidences of benign and malignant tumors of subcutaneous tissue (fibroma and fibrosarcoma) in rats of both sexes and of the blood vessels (hemangioma and hemangiosarcoma) in female mice.

53. The Report also notes that toluene diisocyanates are used primarily to manufacture flexible polyurethane foams for use in furniture, bedding, and automotive and airline seats. The foam in Philips' recalled products is flexible polyurethane foam.

54. The European Union considers toluene diisocyanate "highly toxic" and has concluded that toluene diamine "cannot be considered safe for use" even as a hair dye, let alone breathed into the lungs on a nightly basis for many hours each night.

55. Philips disclosed that it "has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)." The PE-PUR foam is black, and when it breaks down, it can release black particles.

56. The second hazard is the possibility of VOCs, that is, chemical emissions from the PE-PUR foam. Philips explained:

> **Potential Hazard:** Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam included in the CPAP, BiLevel PAP and MV devices and may have short- and long-term adverse health effects.
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> Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:
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> - Dimethyl Diazine
>
> - Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)-

57. Philips admitted that the risks of these VOCs include: "irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve" and may lead to the following symptoms: "headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects," as well as "adverse effects to other organs such as kidney and liver."

58. Corroborating the dangerous nature of the Recalled Products, on July 22, 2021, the FDA upgraded Philips' recall of the Recalled Devices to its most serious classification, Class I, which according to the FDA means: "A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

59. As noted herein, Philips has admitted that the Recalled Products are defective and unsafe. The Recalled Products are therefore worthless and certainly have a far lesser value (zero) than what customers paid and would not have been purchased by patients if they were informed of the defect at the time of sale.

60. The purity of the air coming from a breathing device to a patient is highly important and material to a typical patient. Philips advertises the filtration systems in its devices, for example, noting them on a diagram in its DreamStation Family Brochure.[7] Philips' filtration system, however, does not filter out the particles and VOCs described above.

61. Plaintiff and the Class have suffered injuries as a result of their purchase of the Recalled Products, including substantial economic losses related to their purchase of the Recalled Products and accessories, and replacement machines and accessories, personal injuries, exposure to the toxic foam, and the accompanying need for medical monitoring costs, and losses from not being able to use their machines, including wage loss and other consequential damages.

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7 https://www.documents.philips.com/assets/20180205/15ef65ad106d4ddc88fca87e0134dc60.pdf?_gl=1*1l6jo9f*_ga*MTM1OTI5NDM5Ny4xNjIzODE3MzMz*_ga_2NMXNNS6LE*MTYyNjkxMDEyNC4yMi4xLjE2MjY5MTQyNTkuMjc.&_ga=2.220564312.1106063144.1626914226-1359294397.1623817333.

D. PHILIPS HAS KNOWN ABOUT THE PE-PUR FOAM PROBLEMS FOR YEARS.

62. Although Philips did not disclose these health risks until June 2021, Philips knew about these health risks well beforehand. As discussed above, when Philips announced the recall, Philips also announced that it had received "several complaints" regarding black particles or debris in the airpath circuit. The DreamStation has been on the market since 2015, and several of the affected models have been on the market even longer.

63. Nick Dunn, who runs the YouTube channel "CPAP Reviews," reported as soon as the recall was announced that he had known about the foam issues for several years because he monitors message boards and social media about CPAP machines. It can be reasonably assumed that Philips, like most companies, closely monitored the Internet concerning its products, and heard about foam breakdown and black particles in the machines soon after launch, if not earlier. It can also be reasonably assumed that Philips conducted its own internal studies of its breathing machines and conducted tests and analysis of them that revealed the problems.

64. Message boards still contain many posts about black particles inside or on the filters of the DreamStation and other recalled devices. The following list is provided for illustration.

65. In 2018, the user "trickyneedsleep" reported on apneaboard.com that, using the DreamStation Auto, the filters turned black within three days of use.

66. In 2019, the user "WSHenry" reported on apneaboard.com in a thread entitled "DreamStation Filter Contamination" that "both the pollen and ultra-fine filters in my machine were clogged with black (Carbon?) particles. I also noted that water chamber was completely dry. There were odd odors noted, and the water chamber was undamaged." He explained that he had recently cleaned the filters and that "[t]here was only a small amount of dust on the furniture, and the machine and tubing is clean. I do not burn candles nearby, and the furnace is off. I do have the

window slightly opened, as is the case nearly year-round." He asked: "Is it possible the contamination is from the blower?"

67. In 2019, the user "Skogcat1" reported on apneaboard.com in a thread entitled "Black sticky dust in CPAP machine" that, when using the REMStar Auto, there were "sticky black dust particles" in the humidifier chamber.

68. In September 2020, Carol Nickerson posted on Facebook that she found a black mold-like substance in the water reservoir of her Philips DreamStation. She reported that she cleaned the tubing, mask, and reservoir every week and emptied the reservoir daily, and that she lived in a low-humidity environment in Arizona.

69. In June 2021, shortly after the recall was announced, on a Reddit thread entitled "Dreamstation Foam," user "BOSSHOG999" posted: "I was wondering what the hell those black particles were in my tube."

70. Many of the reports of black particles, dust, or mold in the machines are likely due to the breakdown and disintegration of the defective and poisonous PE-PUR foam in the machines, and it is implausible that Philips, the manufacturer and seller of the machines, was not aware of the complaints and reports.

71. Also, every Philips breathing assistance device since 2009 uses PE-PUR foam, but the DreamStation 2 does not. The implication is clear, and strongly demonstrates that Philips knew that PE-PUR foam was dangerous when it was designing the DreamStation 2, and designed a new product that did not use it.

72. Discovery in this case will pinpoint the exact time when Philips first learned of the potential problems with the poisonous PE-PUR foam that it used in its breathing machines. For example, Philips knew about the foam problems from its own testing of its own products.

Companies that manufacture medical devices certainly perform some testing on the devices before they market them to the public, even if the device is not of the type for which the FDA requires a full demonstration of safety and efficacy.

73. Philips advertises the results of various tests of its products, demonstrating that it tested them in some ways before marketing. For example, Philips advertises that the DreamStation is 63% quieter than a competing product, the ResMed AirSense 10, and is barely louder than a whisper.[8] This relative quietness is in part due to the noise-reducing PE-PUR foam. It is likely that Philips performed many other tests on the PE-PUR foam and uncovered the problems that led to the recall long before the recall.

E. PHILIPS HAS NOT REPLACED THE RECALLED DEVICES AND DOES NOT PLAN TO DO SO IN THE NEAR FUTURE.

74. Philips' CEO, Frans van Houten, stated in the recall announcement: "We deeply regret any concern and inconvenience that patients using the affected devices will experience because of the proactive measures we are announcing today to ensure patient safety."

75. But Philips' "recall" is a "recall" in name only, and does not actually provide patients with new CPAP, BiPAP, or ventilator devices. As Philips' June 14, 2021 announcement explains:

> **Repair and replacement program**
>
> Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible.
>
> As part of the program, the first-generation DreamStation product families will be modified with a different sound abatement foam and shipped upon receipt of the

[8] https://www.documents.philips.com/assets/20170523/62e4f43a1349489ba3cca77c0169c6ef.pdf.

> required regulatory clearances. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected by the issue. To support the program, Philips is increasing the production of its DreamStation 2 CPAP devices, that are available in the US and selected countries in Europe.

76. In reality, patients may register their device with Philips for the recall, but Philips is not currently replacing the defective PE-PUR foam. Nor has Philips provided a timeframe during which it anticipates replacing the defective PE-PUR foam, and it may take a year or more to provide replacements or repairs.

77. Additionally, due to the design of the devices, it is prohibitively difficult for patients to remove or replace the PE-PUR foam themselves. Nor is replacement foam readily available for self-service repairs.

78. But patients need to use their breathing machines every day or else their symptoms—which can be severe and life-altering—may return.

79. As a result, the recall leaves patients without safe, free options. Instead, patients may simply be forced to buy Philips' next-generation product or a competitor's product—at full price, and indeed, thousands of patients, including Plaintiff, have already done so.

80. Thus, Philips intends to, and is, simply profiting from its so-called "recall" by selling more of its next generation product, the DreamStation 2, to affected patients. It appears that Philips intentionally timed the "recall" to coincide with the launch of the DreamStation 2.

81. In its recall announcement, Philips estimated that "the full year comparable sales growth and Adjusted EBITA margin guidance provided on April 26, 2021 remains unchanged." In other words, Philips was stating that it did not expect the recall to impact its bottom line at all. Philips has advised that users should use in-hose filters as a stopgap measure and many users have purchased such filters. There is no proof that the filters are effective, and, according to the FDA,

the filters "will not help to reduce exposure to certain chemicals that may be released from the PE-PUR foam." The filters have to be replaced every couple weeks.

V. CLASS ALLEGATIONS

82. Plaintiff brings this action individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(2) and/or 23(b)(3). Specifically, the Classes that Plaintiff seeks to represent consists of the following:

> **Nationwide Class:** All persons in the United States who have purchased a Recalled Product for personal use.
>
> **Delaware Class:** All persons in Delaware who have purchased a Recalled Products for personal use.

83. The Nationwide Class and Delaware Class are collectively referred to herein as the "Class." Excluded from the Class are Defendants and their employees, officers, and directors; and the Judge(s) and any mediator assigned to this case.

84. Plaintiff reserves the right to redefine the Class prior to class certification.

85. The rights of each member of the Class were violated in a similar fashion based upon Defendants' uniform actions.

86. This action has been brought and may be properly maintained as a class action for the following reasons:

a. Numerosity: Members of the Class are so numerous that their individual joinder is impracticable. The proposed Nationwide Class contains at least millions of individuals, and the proposed Delaware Class contains at least thousands of individuals, who purchased a Recalled Breathing Machine. The Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class members is unknown to Plaintiff at

this time but the Class members are readily ascertainable and can be identified by Defendants' records.

b. Existence and Predominance of Commons Questions of Fact and Law: Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitation:

i. Whether Defendants were unjustly enriched by the sale of the Recalled Products;

ii. Whether Defendants were negligent in selling the Recalled Products;

iii. Whether Defendants failed to warn consumers regarding the risks of the Recalled Products;

iv. Whether Defendants' practices constitute unfair or deceptive acts or practice;

v. The appropriate nature of class-wide equitable relief; and

vi. The appropriate measurement of restitution and/or measure of damages to Plaintiff and members of the Class.

These and other questions of law or fact that are common to the members of the Class predominate over any questions affecting only individual members of the Class.

c. Typicality: Plaintiff's claims are typical of the claims of all members of the Class who purchased the Recalled Products for personal use.

d. Adequacy: Plaintiff is an adequate representative of the Class because his interests do not conflict with the interests of the Class that he seeks to represent; he has retained counsel competent and highly experienced in complex class action litigation, and he intends to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiff and his counsel.

e. Superiority: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiff and the Class. The injury suffered by each Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

VI. EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

87. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from Plaintiff and his medical providers the true risks associated with the Recalled Products.

88. As a result of Defendants' actions, Plaintiff and the Class members were unaware, and could not have reasonably known or learned through reasonable diligence, that they had been exposed to the risks and harms set forth and that those risks and harms were the direct and proximate result of Defendants' acts and omissions.

VII. CAUSES OF ACTION

COUNT I
FAILURE TO WARN

89. Plaintiff and the Class incorporate by reference all preceding paragraphs.

90. Defendants had a duty to warn Plaintiff and the Class members regarding the defect and true risks associated with the Recalled Products.

91. Defendants failed to provide adequate warnings regarding the risks of the PE-PUR foam.

92. Defendants had information regarding the true risks but failed to warn Plaintiff, Class members, and their physicians to strengthen their warnings.

93. Despite Defendants' obligation to unilaterally strengthen the warnings, Philips instead chose to actively conceal this knowledge.

94. Plaintiff and the Class members would not have purchased, chosen, and/or paid for all or part of the Recalled Products if they knew of the defect and the risks of purchasing the product.

95. Defendants owed Plaintiff and Class Members a duty of care and to warn of any risks associated with the Recalled Products. Defendants knew or should have known of the true risks but failed to warn Plaintiff, Class members, and their doctors.

96. This defect proximately and Defendant's negligent breach of its duties caused Plaintiff's and Class members' injuries which include economic injuries, as well as headache, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

97. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT II
DESIGN DEFECT

98. Plaintiff and the Class incorporate by reference all preceding paragraphs.

99. Defendants negligently designed the Recalled Products. Philips owed Plaintiff and the Class a duty to design the Recalled Products in a reasonable manner.

100. The design of the Recalled Products, including but not limited to design and use of the PE-PUR foam and the placement of the foam within the Recalled Products, was defective and unreasonably dangerous, causing degradation and inhalation of the PE-PUR foam, and causing headaches, irritation, inflammation, respiratory issues, and exposure to materials with toxic and carcinogenic effects.

101. The design of the Recalled Products and the PE-PUR foam rendered the Recalled Products not reasonably fit, suitable, or safe for their intended purpose.

102. The dangers of the Recalled Products outweighed the benefits and rendered the products unreasonably dangerous. Indeed, there are other CPAP and other machines that do not use a similarly toxic foam that is subject to degradation, inhalation, and ingestions.

103. Safer alternative machines were available that did not suffer from the defect as set forth herein and that did not have an unreasonable risk of harm as with the Recalled Products and their unsafe PE-PUR foam, for example machines made by other manufacturers.

104. The risk benefit profile of the Recalled Products was unreasonable, and the products should have had stronger and clearer warnings or should not have been sold in the market.

105. The Recalled Products did not perform as an ordinary consumer would expect.

106. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT III
NEGLIGENT RECALL

107. Plaintiff and the Class incorporate by reference all preceding paragraphs.

108. In issuing a voluntary recall, Philips assumed duties to Plaintiff and the Class to exercise reasonable care in issuing and implementing the recall.

109. Philips breached its duties by failing to adequately warn Plaintiff and the Class of the dangers associated with the use of the Recalled Products by refusing to promptly repair or replace the Recalled Products.

110. As a direct result of Defendants' breach of duty, Plaintiff and the Class have suffered harm in an amount to be determined at trial.

COUNT IV
BREACH OF EXPRESS WARRANTY

111. Plaintiff and the Class incorporate by reference all preceding paragraphs.

112. Defendants warranted the Recalled Products "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."

113. Defendants breached this express warranty in connection with the sale and distribution of the Recalled Products At the point of sale, the Recalled Products while appearing normal—contained immediate defects as set forth herein, rendering them unsuitable and unsafe for personal use by humans.

114. Had Plaintiff and the Class known the Recalled Products were unsafe for use, they would not have purchased them.

115. Defendants have breached their warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Products. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Products were safe for their ordinary and intended use.

116. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT V
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

117. Plaintiff and the Class incorporate by reference all preceding paragraphs.

118. By operation of law, Defendants, as manufacturers of the Recalled Products and as the providers of a limited warranty for the Recalled Products, impliedly warranted to Plaintiff and the Class that the Recalled Products were of merchantable quality and safe for their ordinary and intended use.

119. Defendants breached the implied warranty of merchantability in connection with the sale and distribution of the Recalled Products. At the point of sale, the Recalled Products while appearing normal—contained defects as set forth herein rendering them unsuitable and unsafe for personal use by humans.

120. Had Plaintiff and the Class known the Recalled Products were unsafe for use, they would not have purchased them.

121. Defendants have refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Products. Plaintiff and the Class reasonably expected, at the time of purchase, that the Recalled Products were safe for their ordinary and intended use.

122. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT VI
Delaware Consumer Fraud Act
Del. Code Ann. § 2511, *et seq.*
On Behalf of the Delaware Subclass

123. Plaintiff incorporates by reference all preceding paragraphs.

124. Plaintiff brings this cause of action individually and on behalf of the members of the Delaware Subclass.

125. The Delaware Consumer Fraud Act prohibits "the act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale . . . of any merchandise." Del. Code Ann. § 2513.

126. Defendants participated in unfair or deceptive trade practices that violated the Delaware Consumer Fraud Act as described below and alleged throughout the Complaint. By concealing the true risks of the Recalled Products, Defendants knowingly and intentionally misrepresented and omitted material facts in connection with the sale the Recalled Products. Defendants systematically misrepresented, concealed, suppressed, or omitted material facts relating to the Recalled Products in the course of their business.

127. Defendants also engaged in unlawful trade practices by employing deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale of the Recalled Products.

128. Defendants' unfair and deceptive acts or practices occurred repeatedly in Defendants' trade or business, were capable of deceiving a substantial portion of the purchasing public, and imposed a serious safety risk on the public.

129. Defendants knew that the risks inherent in the Recalled Products made them not suitable for their intended use.

130. Defendants knew or should have known that their conduct violated the Delaware Consumer Fraud Act.

131. Had Plaintiff and the Delaware Subclass Members known the truth about the Recalled Products, they would not have obtained the Recalled Products. Plaintiff and the Delaware Subclass did not receive the benefit of their bargain as a result of Defendants' misconduct.

132. Defendants owed Plaintiff and the Delaware Subclass Members a duty to disclose the truth about the Recalled Products because Defendants: (a) possessed exclusive, specific and superior knowledge of the true risks of the Recalled Products; (b) intentionally concealed the foregoing from Plaintiff and the Delaware Subclass Members; and/or (c) made incomplete representations regarding the Recalled Products, while purposefully withholding material facts from Plaintiff and the Delaware Subclass Members that contradicted these representations.

133. Plaintiff and the Delaware Subclass Members suffered monetary damages as a result of Defendants' conduct.

134. Defendants' violations present a continuing risk to Plaintiff and the Delaware Subclass Members, as well as to the general public. Defendants' unlawful acts and practices complained of herein affect the public interest.

135. Defendants are liable to Plaintiff and the Delaware Subclass Members for all damages sustained. Del. Code Ann. § 2525.

COUNT VII
UNJUST ENRICHMENT
(In the Alternative)
On Behalf of the Nationwide Class

136. Plaintiff and the Class incorporate by reference all preceding paragraphs.

137. Plaintiff and the Class members conferred a tangible and material economic benefit upon Defendants by purchasing the Recalled Products. Plaintiff and Class members would not have purchased, chosen and/or paid for all or part of Recalled Products had they known the true risks of using the Recalled Products. Defendants are not providing a timely repair or replacement for the Recalled Products. Under these circumstances, it would be unjust and inequitable for Defendants to retain the economic benefits they received at the expense of Plaintiff and the Class.

138. Failing to require Defendants to provide remuneration under these circumstances would result in Defendants being unjustly enriched at the expense of Plaintiff and the Class members who endure being exposed to the risk of developing serious medical conditions and can no longer use their Recalled Products safely.

139. Defendants' retention of the benefit conferred upon them by Plaintiff and the Class would be unjust and inequitable.

140. Plaintiff and the Class suffered damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests, individually and on behalf of the Class, that this Court:

A. determine that the claims alleged herein may be maintained as a class action under Rule 23(a), (b)(2), and/or (b)(3) of the Federal Rules of Civil Procedure on behalf of the Nationwide Class and state subclasses defined above, and designate Plaintiff as the class representative, and Plaintiff's counsel as Class Counsel;

B. award equitable and injunctive relief, including but not limited to, requiring Defendants to institute a medical monitoring program for Plaintiff and Class members, restitution, and disgorgement of profits;

C. award all actual, general, special, incidental, punitive, and consequential damages to which Plaintiff and Class members are entitled;

D. award pre-judgment and post-judgment interest on such monetary relief;

E. award reasonable attorneys' fees and costs; and

F. grant such further and other relief that this Court deems appropriate.

JURY DEMAND

Plaintiff and the Class demand a trial by jury on all issues so triable.

Date: October 11, 2021

/s/Shanon J. Carson

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